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**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

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**UNITED STATES OF AMERICA,**  
**Plaintiff,**

**v.**

**PHARMACEUTICAL INNOVATIONS,**  
**INC., a corporation, and GILBERT**  
**BUCHALTER, an individual,**  
**Defendants.**

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**Civil Action No.**

**COMPLAINT FOR PERMANENT INJUNCTION**

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the “Act”), 21 U.S.C. § 332(a), to enjoin Pharmaceutical Innovations, Inc. (“PI”), a corporation, and Gilbert Buchalter, an individual, from violating:

A. 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and/or causing the introduction or delivery for introduction into interstate commerce, articles of device, as defined by 21 U.S.C. § 321(h), that are adulterated within the meaning of:

i. 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, and installation are not in conformity with current good manufacturing practice (“CGMP”) requirements in 21 U.S.C. § 360j(f)(1) and the implementing quality system regulation at 21 C.F.R. Part 820; and

ii. 21 U.S.C. § 351(f)(1)(B), in that they are Class III devices pursuant to 21 U.S.C. § 360c(f), and there are no approved applications for premarket approval (“PMA”) on file with the United States Food and Drug Administration (“FDA”) as required by 21 U.S.C. § 360e(a), and the devices do not have an approved application for an investigational device exemption under 21 U.S.C. § 360j(g);

B. 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and/or causing the introduction or delivery for introduction into

interstate commerce, articles of devices, as defined by 21 U.S.C. § 321(h), that are misbranded within the meaning of:

i. 21 U.S.C. § 352(o), in that Defendants fail to provide notice or other information respecting their devices to FDA as required by 21 U.S.C. § 360(k); and

ii. 21 U.S.C. § 352(t)(2), in that Defendants fail to furnish material or information respecting their devices to FDA as required by 21 U.S.C. § 360i and the implementing regulations set forth in 21 C.F.R. Parts 803 and 806;

C. 21 U.S.C. § 331(k), by causing devices to become adulterated within the meaning of 21 U.S.C. § 351(h) and 21 U.S.C. § 351(f)(1)(B), as described in paragraph A above, and misbranded within the meaning of 21 U.S.C. § 352(o) and 21 U.S.C. § 352(t)(2), as described in paragraph B above, while such devices are held for sale after shipment of one or more of their components in interstate commerce;

D. 21 U.S.C. § 331(p), by failing to provide information required by 21 U.S.C. § 360(k); and

E. 21 U.S.C. § 331(q)(1)(B), in that Defendants fail to furnish notification or other material or information to FDA as required by 21 U.S.C. § 360i and the implementing regulations set forth in 21 C.F.R. Parts 803 and 806.

#### JURISDICTION AND VENUE

2. This Court has jurisdiction pursuant to 21 U.S.C. § 332(a) and 28 U.S.C. §§ 1331 and 1345.

3. Venue in this District is proper pursuant to 28 U.S.C. § 1391(b) and (c).

### DEFENDANTS

4. Defendant PI is located at 897 Frelinghuysen Avenue, Newark, New Jersey, and is incorporated under the laws of New Jersey. PI manufactures, markets, sells, and distributes medical devices, including ultrasound, mammography, and electrocardiogram gels, scanning pads, and sprays.

5. Defendant Gilbert Buchalter is the founder and owner of PI. For many years, he served as the company's president and sole director and was the most responsible person at the company, with all personnel reporting to him. In September 2014, on information and belief, the company elected two additional Directors; designated Defendant Gilbert Buchalter as Chairman of the Board of Directors; and appointed a new president. As of the date of filing this Complaint, October 2, 2014, the New Jersey Treasury Department certifies that Defendant Gilbert Buchalter was the only officer or director on Pharmaceutical Innovations' most recent annual report, filed August 6, 2014. (Exhibit 1.) On information and belief, Defendant Gilbert Buchalter continues to have responsibility for and authority over the company's operations.

### DEFENDANTS' DEVICES

6. Defendants' products are devices, within the meaning of 21 U.S.C. § 321(h), in that Defendants' products are accessories to instruments intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man, which do not achieve their primary intended purposes through chemical action or on the body of man and which are not dependent upon being metabolized for the achievement of their primary intended purposes.

7. Examples of Defendants' devices include Ultra Phonic Conductivity Gel (in the 20 mL sterile packet), Ultra Phonic Focus Pad, Ultra Phonic Fontanelle Scanning Pad, Ultra

Phonic Ophthalmic Scanning Pad, Ultra Phonic Free, Ultra Phonic Scanning Gel, Ultra Phonic Conductivity Gel (non-sterile), and Other-Sonic Generic Ultrasound Transmission Gel.

8. Defendants distribute their devices in interstate commerce. In addition, components from states outside New Jersey are shipped to Defendants and used in the manufacture of their devices.

#### PROHIBITED ACTS

9. It is a violation of the Act to introduce or deliver for introduction into interstate commerce an adulterated or misbranded article of device. 21 U.S.C. § 331(a).

10. It is a violation of the Act to do any act with respect to a device that, while it is held for sale after shipment of one or more of its components in interstate commerce, causes the device to become adulterated or misbranded. 21 U.S.C. § 331(k).

11. It is a violation of the Act to fail to provide any information required by 21 U.S.C. § 360(k). 21 U.S.C. § 331(p).

12. It is a violation of the Act to fail or refuse to furnish any notification or other material or information required under 21 U.S.C. § 360i, and the implementing regulations at 21 C.F.R. Parts 803 and 806. 21 U.S.C. § 331(q)(1)(B).

#### CGMP VIOLATIONS

13. The Act requires the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation, packing, storage, and installation of a device to conform to CGMP to assure the device's safety and effectiveness. 21 U.S.C. § 360j(f). The statutory CGMP requirements are set out in the quality system regulation for devices, 21 C.F.R. Part 820. Devices that are not manufactured, packed, stored, and installed in conformance with CGMP are deemed to be adulterated. 21 U.S.C. § 351(h).

14. FDA inspected PI's facility from March 22, 2013, through April 3, 2013 ("March–April 2013 Inspection"). During this inspection, the FDA investigators documented Defendants' failures to comply with CGMP in 21 U.S.C. § 360j(f)(1) and the quality system regulation set forth in 21 C.F.R. Part 820, including that:

A. Defendants fail to comply with the process validation requirements set forth at 21 C.F.R. § 820.75(a). For example, Defendants have not shown that they have validated the dry heat sterilization and dry heat treatment processes that they apply to their products;

B. Defendants fail to comply with production and process control requirements set forth at 21 C.F.R. § 820.70(a). For example, Defendants have not shown that they routinely monitor their water systems to ensure that the water is suitable for manufacturing medical devices;

C. Defendants fail to comply with production and process control requirements relating to contamination control set forth at 21 C.F.R. § 820.70(e). For example, Defendants have not shown that they routinely sanitize the tubing and connections of their water systems to ensure objectionable microorganisms do not reside in the inner piping surface;

D. Defendants fail to comply with corrective and preventive action requirements set forth at 21 C.F.R. § 820.100(a). For example, Defendants have not shown that they have validated the heat treatments they instituted as corrective actions in response to a February 2012 hospital report identifying bacterial contamination in their Other-Sonic Generic Ultrasound Transmission Gel; and

E. Defendants fail to comply with purchasing control requirements set forth at 21 C.F.R. § 820.50(a). For example, Defendants have not shown that their microbial testing laboratory uses a validated microbial testing method suitable for testing their medical devices.

15. At the conclusion of the March–April 2013 Inspection, FDA investigators issued Pharmaceutical Innovation’s plant manager a form FDA 483, List of Inspectional Observations (“Form FDA 483”), detailing Defendants’ deviations from CGMP, and discussed the documented observations with him.

16. FDA also inspected PI from October 2, 2012, through November 6, 2012 (“October–November 2012 Inspection”); from February 13, 2012, through February 27, 2012 (“February 2012 Inspection”); and from April 14, 2011, through May 16, 2011 (“April–May 2011 Inspection”). During each of those inspections, the FDA investigators observed and documented violations of the quality system regulation similar to those described in paragraph 14, including, but not limited to, violations involving the following: process validation (21 C.F.R. § 820.75), production and process controls (21 C.F.R. § 820.70), corrective and preventive action (21 C.F.R. § 820.100), and purchasing controls (21 C.F.R. § 820.50). At the conclusion of each of those inspections, FDA investigators issued a Form FDA 483 to Gilbert Buchalter detailing Defendants’ numerous deviations from CGMP and discussed the documented observations with Gilbert Buchalter.

#### LACK OF PREMARKET APPROVAL AND NOTIFICATION

17. In general, devices introduced or delivered for introduction into interstate commerce for commercial distribution after May 28, 1976, are automatically classified as Class III as a matter of law, 21 U.S.C. § 360c(f)(1), unless the sponsor of a device (1) obtains an order

from FDA finding that the device is “substantially equivalent” to a legally-marketed predicate device that does not require premarket approval (commonly known as a “cleared 510(k) premarket notification submission” or “510(k)”), 21 U.S.C. §§ 360c(f)(1), 360c(i), 360e(a)(2) and (b), 360(k), or (2) has the device classified or reclassified in Class I or Class II under 21 U.S.C. §§ 360c(f)(2) or (f)(3). With certain exceptions not applicable here, Class III devices under 21 U.S.C. § 360c(f)(1) must have an approved application for PMA prior to marketing, 21 U.S.C. § 360e(a).

18. A device classified as Class III under 21 U.S.C. § 360c(f) is deemed to be adulterated if: (1) it is required to have in effect an approved application for PMA under 21 U.S.C. § 360e(a); (2) there is no FDA-approved PMA application in effect; and (3) there is not an approved application for an investigational device exemption (“IDE”) under 21 U.S.C. § 360j(g). 21 U.S.C. § 351(f)(1)(B).

19. Manufacturers who are required to register with FDA and who propose to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use are required to submit a premarket notification to FDA at least ninety days before making such introduction. 21 U.S.C. § 360(k). An owner or operator of an establishment not exempt under 21 U.S.C. § 360(g) or 21 C.F.R. § 807.65 who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use must register with FDA. 21 C.F.R. § 807.20.

20. Premarket notification is required for any device that is

A. being introduced into commercial distribution for the first time (21 C.F.R. § 807.81(a)(1));

B. currently in commercial distribution, but is significantly changed or modified in design, components, or methods of manufacture such that the change could significantly affect the safety or effectiveness of the device (21 C.F.R. § 807.81(a)(3)(i)); or

C. currently in commercial distribution, but has a major change or modification in its intended use (21 C.F.R. § 807.81(a)(3)(ii)).

21. A device is deemed to be misbranded if a premarket notification was not submitted to FDA as required by 21 U.S.C. § 360(k). 21 U.S.C. § 352(o).

22. A device may be considered “grandfathered,” and thus not subject to the premarket review requirements, if it was legally marketed in the United States by a particular firm prior to the enactment of the Medical Device Amendments of 1976, Pub. L. No. 94-295, § 2, 90 Stat. 539, on May 28, 1976 (commonly known as a “preamendment device”) and it has not been significantly changed or modified since that date, and if FDA has not promulgated a regulation requiring an application for PMA for that type of device.

23. Defendants are distributing Class III devices under 21 U.S.C. § 360c(f)(1) for which they do not have an approved application for PMA pursuant to 21 U.S.C. § 360e(a), a cleared 510(k) pursuant to 21 U.S.C. §§ 360(k) and 360c(i), or an approved application for an investigational device exemption (“IDE”) under 21 U.S.C. § 360j(g). Defendants’ devices are not grandfathered because Defendants have failed to demonstrate that these exact devices were introduced into interstate commerce for commercial distribution prior to May 28, 1976, or that these devices have not been significantly changed or modified from devices Defendants commercially distributed prior to May 28, 1976. The currently marketed devices differ from the devices that the Defendants have claimed to be preamendment devices, and such changes or

modifications could significantly affect the safety and/or effectiveness of the devices. For example,

A. Defendants do not have an approved application for PMA or IDE or a cleared 510(k) for their Ultra Phonic Conductivity Gel (in the 20 mL sterile packet). Defendants have failed to establish that they introduced the Ultra Phonic Conductivity Gel (in the 20 mL sterile packet) into interstate commerce for commercial distribution before May 28, 1976. In addition, the manufacturing process of the Ultra Phonic Conductivity Gel (in the 20 mL sterile packet) differs from that of the devices Defendants have claimed are preamendment devices in a way that could significantly affect the safety or effectiveness of the device. Specifically, the manufacturing process of the Ultra Phonic Conductivity Gel includes a sterilization step, whereas the manufacturing processes of the devices Defendants have claimed are preamendment devices do not include a sterilization step, and sterilization could significantly affect the safety and effectiveness of the device;

B. Defendants do not have an approved application for PMA or IDE or a cleared 510(k) for their Ultra Phonic Focus Pad, Ultra Phonic Fontanelle Scanning Pad, and Ultra Phonic Ophthalmic Scanning Pad (“Pad Devices”). Defendants have failed to establish that they introduced the Pad Devices into interstate commerce for commercial distribution before May 28, 1976. In addition, the design and manufacturing processes of the Pad Devices differ from those of the devices Defendants have claimed are preamendment devices in a way that could significantly affect the safety or effectiveness of the Pad Devices. Specifically, the Pad Devices are solid gel pads, whereas the devices

Defendants have claimed are preamendment devices are liquid gels, and the change from a liquid to solid gel could significantly affect the safety and effectiveness of the devices;

C. Defendants do not have an approved application for PMA or IDE or a cleared 510(k) for their Ultra Phonic Free gel. Defendants have failed to establish that they introduced Ultra Phonic Free into interstate commerce for commercial distribution before May 28, 1976. In addition, the chemical composition and the manufacturing process of the Ultra Phonic Free differ from that of the devices Defendants have claimed are preamendment devices in a way that could significantly affect the safety or effectiveness of the device. Specifically, the Ultra Phonic Free contains a different preservative than the one in the devices Defendants have claimed are preamendment devices, and the change in preservative could significantly affect the safety and effectiveness of the device; and

D. Defendants do not have an approved application for PMA or IDE or a cleared 510(k) for Ultra Phonic Scanning Gel, Ultra Phonic Conductivity Gel (non-sterile), or Other-Sonic Generic Ultrasound Transmission Gel. Defendants have failed to establish that they introduced Ultra Phonic Scanning Gel, Ultra Phonic Conductivity Gel (non-sterile), or Other-Sonic Generic Ultrasound Transmission Gel into interstate commerce for commercial distribution before May 28, 1976. In addition, the manufacturing processes of Ultra Phonic Scanning Gel, Ultra Phonic Conductivity Gel (non-sterile), and Other-Sonic Generic Ultrasound Transmission Gel differ from that of the devices Defendants have claimed are preamendment devices in a way that could significantly affect the safety or effectiveness of the devices. Specifically, the manufacturing processes of Ultra Phonic Scanning Gel, Ultra Phonic Conductivity Gel

(non-sterile), and Other-Sonic Generic Ultrasound Transmission Gel include a dry heat treatment step, whereas the manufacturing processes of the devices Defendants have claimed are preamendment devices do not include a dry heat treatment step, and the dry heat treatment step could significantly affect the safety and effectiveness of the devices.

24. Defendants have introduced into interstate commerce for commercial distribution devices intended for human use without submitting premarket notifications for those devices. Defendants are not exempt from the registration requirements under 21 U.S.C. § 360(g) or 21 C.F.R. § 807.65, and they are engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use. 21 C.F.R. § 807.20.

#### FAILURE TO COMPLY WITH REPORTING REQUIREMENTS

25. Every manufacturer of a device intended for human use is required to submit certain reports to FDA, as required by regulation, to assure that the device is not adulterated or misbranded and to otherwise assure its safety and effectiveness. 21 U.S.C. § 360i(a).

26. Every manufacturer of a device is required to submit a medical device report (“MDR” or “report”) to FDA within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that the marketed device may have caused or contributed to a death or serious injury, and to adequately develop, maintain, and implement written MDR procedures. 21 C.F.R. §§ 803.50(a), 803.17(a).

27. Every manufacturer of a device must submit a written report to FDA of any correction or removal of a device initiated by such manufacturer, within 10 working days of initiating such correction or removal, if the correction or removal was initiated (1) to reduce a risk to health posed by the device; or (2) to remedy a violation of the FDCA caused by the device which may present a risk to health unless the information has already been provided to FDA in

an MDR (21 C.F.R. Part 803) or in a plan for replacement, repair, or refund of electronic products (21 C.F.R. Part 1004) or the corrective or removal action is exempt from the reporting requirements. 21 C.F.R. § 806.10.

28. A device is deemed to be misbranded, pursuant to 21 U.S.C. § 352(t)(2), if its manufacturer fails or refuses to furnish any material or information required by or under 21 U.S.C. § 360i, including if a manufacturer fails to submit reports to FDA as required by 21 C.F.R. Parts 803 and 806.

29. Defendants failed to comply with the reporting requirements set forth at 21 C.F.R. Part 803, including that:

a. Defendants failed to submit an MDR within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that their marketed device may have caused or contributed to a serious injury, as required by 21 C.F.R. § 803.50(a)(1). Specifically, Defendants did not submit MDRs to FDA after becoming aware in February 2012 of *Pseudomonas aeruginosa* infections in surgical patients at a hospital in Michigan who had undergone a procedure involving Defendants' Other-Sonic Generic Ultrasound Transmission Gel; and

b. Defendants failed to adequately develop, maintain, and implement written MDR procedures, as required by 21 C.F.R. § 803.17(a). For example, Defendants' MDR procedure does not address how Defendants will submit all information reasonably known to it for each reportable event and the circumstances under which Defendants must submit supplemental or follow-up reports and the requirements for such reports.

30. Defendants failed to comply with the reporting requirements set forth at 21 C.F.R. Part 806 in that Defendants failed to submit a written report to FDA within 10 days of the

correction or removal of devices it initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device which may present a risk to health, as required by 21 C.F.R. § 806.10(a). Specifically, Defendants have not submitted a report to FDA about its removal of lots of Other-Sonic Generic Ultrasound Transmission Gel that Defendants learned in February 2012 were associated with the *Pseudomonas aeruginosa* infections of surgical patients at the hospital in Michigan.

#### PRIOR NOTICE OF VIOLATIONS

31. Defendants are well aware that their practices violate the Act. FDA has repeatedly warned Defendants, both orally and in writing, about their violative conduct, and has emphasized the importance of Defendants' compliance with the Act.

32. At the conclusion of the April–May 2011 inspection, FDA investigators issued a Form FDA 483 detailing Defendants' various violations of the Act, and discussed the documented observations with Gilbert Buchalter.

33. On July 29, 2011, FDA issued a Warning Letter to Defendants, stating that Defendants' devices were adulterated under 21 U.S.C. 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, and installation are not in conformity with CGMP requirements under 21 U.S.C. § 360j(f)(1) and the implementing quality system regulation at 21 C.F.R. Part 820.

34. On February 1, 2012, FDA met with Defendants to discuss their CGMP deficiencies.

35. On February 15, 2012, FDA received a report from a hospital in Michigan involving 16 surgical patients infected with *Pseudomonas aeruginosa*. The hospital determined that the most likely source of the bacteria was PI's ultrasound sound transmission gel, Other-

Sonic Generic Ultrasound Transmission Gel. FDA tested samples of PI's Other-Sonic Generic Ultrasound Transmission Gel, and FDA's analysis of the samples confirmed the presence of significant amounts of *Pseudomonas aeruginosa* and *Klebsiella oxytoca*, which pose serious risks of infection to individuals exposed to the product. On April 16, 2012, the United States filed a Verified Complaint for Forfeiture *In Rem* against the relevant lots of PI's Other-Sonic Generic Ultrasound Transmission Gel, and the U.S. Marshal seized the lots on April 17, 2012. *See United States v. All Articles of Other-Sonic Generic Ultrasound Transmission Gel . . . . Manufactured by Pharmaceutical Innovations . . .*, Civil Action No. 12-2264 (ES) (D.N.J.).

36. At the conclusion of FDA's February 2012 inspection, FDA investigators issued a Form FDA 483 detailing Defendants' various violations of the Act, and discussed the documented observations with Gilbert Buchalter.

37. At the conclusion of FDA's October–November 2012 inspection, FDA investigators issued a Form FDA 483 detailing Defendants' various violations of the Act, and discussed the documented observations with Gilbert Buchalter.

38. On February 8, 2013, FDA sent a letter to Defendants, stating that many of Defendants' ultrasound devices appear to require premarket notification submissions and requesting that Defendants provide FDA with documentation demonstrating that such submissions are not required.

39. At the conclusion of FDA's March–April 2013 inspection, FDA investigators issued a Form FDA 483 detailing Defendants' various violations of the Act, and discussed the documented observations with Pharmaceutical Innovations' plant manager. Also, during FDA's March–April 2013 inspection, pursuant to a Court-issued administrative warrant, FDA obtained quality system records, including device formulations, that Defendants had refused to provide to

FDA investigators during prior inspections. *See In the Matter of Establishment Inspection of Pharmaceutical Innovations, Inc.* . . . , Mag. No. 13-3581 (D.N.J.).

40. On March 27, 2014, at the U.S. Courthouse for the United States District Court for the District of New Jersey, FDA representatives met with Defendants to discuss their CGMP deficiencies and Defendants' marketing of devices without the required approval or clearance.

41. On June 26, 2014, FDA sent a letter to Defendants detailing the deficiencies in Defendants' April 5, 2013 submission to FDA, and April 9, 2014, supplemental submission to FDA and concluding that Defendants had not adequately addressed or corrected the FDA observations from the March–April 2013 inspection.

42. Despite numerous warnings from FDA over the past three years and Defendants' promises to correct the numerous ongoing violations, Defendants continue to violate the Act, as observed in FDA's March–April 2013 inspection; Defendants' April 5, 2013, and April 9, 2014 submissions to the Agency relating to the CGMP deficiencies; and Defendants' March 4, 2013, and June 26, 2014 submissions to FDA relating to their marketing of devices without premarket approval or clearance.

43. Based on Defendants' conduct, Plaintiff believes that, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. §§ 331(a), (k), (p), and (q).

WHEREFORE, Plaintiff prays:

I. That Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, be permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a) and the inherent equitable authority of this Court, from directly or indirectly:

A. violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, and/or causing the introduction or delivery for introduction into interstate commerce, any article of device that is adulterated within the meaning of 21 U.S.C. §§ 351(h) and 351(f)(1)(B) or misbranded within the meaning of 21 U.S.C. §§ 352(o) and 352(t)(2);

B. violating 21 U.S.C. § 331(k), by causing any article of device to become adulterated within the meaning of §§ 351(h) and 351(f)(1)(B), or misbranded within the meaning of 21 U.S.C. §§ 352(o) and 352(t)(2), while such article is held for sale after shipment of one or more of its components in interstate commerce;

C. violating 21 U.S.C. § 331(p), by failing to provide information required by 21 U.S.C. § 360(k); and

D. violating 21 U.S.C. § 331(q)(1)(B), by failing to provide information required by 21 U.S.C. § 360i.

II. That the Court order Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, to cease directly or indirectly manufacturing, packing, labeling, and distributing (domestically and internationally) any device, unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute devices are established, operated, and administered in compliance with CGMP requirements in 21 U.S.C. § 360j(f)(1) and the quality system regulation in 21 C.F.R. Part 820, and in a manner that has been found acceptable to FDA;

B. Defendants ensure that, for each device requiring premarket approval or 510(k) clearance that the Defendants have introduced into interstate commerce for

commercial distribution or propose to introduce into interstate commerce for commercial distribution, they have obtained the appropriate premarket approval or 510(k) clearance from FDA and that the device is introduced into interstate commerce for commercial distribution in accordance with such clearance or approval; and

C. Defendants comply with the reporting requirements set forth in 21 U.S.C. § 360i and 21 C.F.R. Parts 803 and 806.

III. That the Court authorize FDA, pursuant to this injunction, to inspect Defendants' place of business to ensure continuing compliance with the terms of this injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are performed.

IV. That Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

Respectfully submitted,

Dated: October 2, 2014

**FOR THE UNITED STATES OF  
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